K110617

JUN - 2 2011

SECTION 2 – 510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR 807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. SUBMITTER'S NAME	Abbott Vascular
2. SUBMITTER'S ADDRESS	26531 Ynez Road, Temecula, CA 92591
3. TELEPHONE	(951) 914-3243
4. FAX	(951) 914-0339
5. CONTACT PERSON	Suzanne Redman
6. DATE PREPARED	March 2, 2011
7. DEVICE TRADE NAME	• MINI TREK™ RX 1.20 mm Coronary Dilatation Catheter • MINI TREK™ OTW 1.20 mm Coronary Dilatation Catheter
8. DEVICE COMMON NAME	• Coronary Dilatation Catheter • Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
9. DEVICE CLASSIFICATION NAME	PTCA Catheter, LOX, Class II, 21 CFR 870.5100
10. PREDICATE DEVICE NAME	• MINI TREK™ RX Coronary Dilatation Catheter • TREK™ RX Coronary Dilatation Catheter • MINI TREK™ OTW Coronary Dilatation Catheter • TREK™ OTW Coronary Dilatation Catheter

11. DEVICE DESCRIPTION

11.1 MINI TREK RX 1.20 mm Coronary Dilatation Catheter

The MINI TREK RX 1.20 mm Coronary Dilatation Catheter is a rapid exchange co-axial design with a balloon at the distal tip. **Table 2-1** provides a matrix of the balloon diameters

and lengths available for the complete TREK RX family of devices, including the addition of the 1.20 mm balloon diameter.

Table 2-1 MINI TREK RX & TREK RX Size Matrix

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK RX							
1.20	*New*	*New*	*New*	*New*	*New*		
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X
TREK RX							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50			X	X			
5.00			X	X			

The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. All 1.20 mm balloon diameters have a single balloon marker. The co-axial shaft consists of a tubular inner and outer member. The inner member permits the use of a guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. The proximal shaft consists of a hypotube with a hub on the proximal end, a tapered distal section ending distal to the guide wire notch junction, along with brachial and femoral markers.

11.2 MINI TREK OTW 1.20 mm Coronary Dilatation Catheter

The MINI TREK OTW 1.20 mm Coronary Dilatation Catheter is an over-the-wire (OTW) co-axial design with a balloon at the distal tip. **Table 2-2** provides a matrix of the balloon diameters and lengths available for the complete TREK OTW family of devices, including the addition of the 1.20 mm balloon diameter.

Table 2-2 MINI TREK OTW & TREK OTW Size Matrix

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK OTW							
1.20	*New*	*New*	*New*	*New*	*New*		
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X
TREK OTW							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50			X	X			
5.00			X	X			

The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. All 1.20 mm balloon diameters have a single balloon marker. The co-axial shaft consists of a tubular inner and outer member. The inner lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. Along the proximal portion of the shaft are brachial and femoral markers to aid in gauging the catheter's position relative to the guiding catheter tip when introducing the catheter through the guiding catheter. An adaption arm is located at the proximal end to provide access to the inflation lumen and guide wire lumen and allows connection with an inflation device.

12. INDICATIONS FOR USE

The MINI TREK™ RX 1.20 mm Coronary Dilatatoin Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).

The MINI TREK™ OTW 1.20 mm Coronary Dilatatoin Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).

13. TECHNOLOGICAL CHARACTERISTICS

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

14. PERFORMANCE DATA

14.1 Summary of Biocompatibility Testing

Biocompatibility testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, and complement activation according to the recommendations of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010 and ISO 10993-1:2003, *Biological evaluation of medical devices – Part 1: Evaluation and testing*.

14.2 Summary of *In Vitro* Bench Testing

The MINI TREK RX 1.20 mm and MINI TREK OTW 1.20 mm Coronary Dilatation Catheters were subjected to the following *in vitro* bench tests according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010:

- Catheter Preparation
- Balloon Crossing Profile
- Refolded Balloon Profile
- Balloon Inflation / Balloon Deflation
- Balloon Fatigue
- Balloon Rupture
- Balloon Compliance
- Catheter Shaft Fatigue
- Catheter Shaft Rupture
- Soft Tip to Inner Member Tensile
- Proximal Balloon Seal Tensile
- Kink and Flexibility
- Torque

14.3 Summary of Clinical Data

14.3.1 Study Purpose

The objective of this trial was to evaluate the acute safety and efficacy of the MINI TREK RX 1.20 mm Coronary Dilatation Catheter (CDC) for enlarging coronary luminal diameter during percutaneous coronary intervention (PCI) procedures in subjects with ischemic heart disease due to stenotic lesions.

14.3.2 Design

The CROSS clinical trial was a prospective, open-label, single-arm, multi-center, observational study. Approximately 60 subjects were to be enrolled at 4 clinical sites in the US; 71 subjects were enrolled to compensate for some subjects who did not have a creatine kinase myocardial-band isoenzyme (CK-MB) draw at or later than 16 hours post-index procedure. Each subject was allowed a maximum of two lesions, including at least one target lesion, in up to two major epicardial distribution trees. Subjects with single or dual vessel disease and clinical evidence of myocardial ischemia were included in the trial. Subjects with recent AMI (within 72 hours of index or new onset) were excluded. The target lesions were allowed to be de novo or restenotic lesions in native coronary arteries or bypass grafts with $\geq$ 70% stenosis, which may include chronic total occlusion (CTO).

The target lesion in this trial was defined as a lesion intended to be initially pre-dilated during the index procedure with a MINI TREK RX 1.20 mm balloon. Any commercially available coronary dilatation catether could have been used for further dilatation as needed. The non-target lesion in this trial was defined as a lesion intended to be initially treated with any commercially available device.

The primary endpoint was procedure success, which was defined as meeting all of the following after single or multiple attempts with the use of the MINI TREK RX 1.20 mm balloon:

- Successful delivery of the MINI TREK RX 1.20 mm balloon to and across the target lesion,
- Successful inflation and deflation with the MINI TREK RX 1.20 mm balloon,
- No vessel perforation, no flow-limiting vessel dissection, no reduction in thrombolysis in myocardial infarction (TIMI) flow from baseline, and no clinically significant arrhythmias requiring medical treatment or device intervention following dilatation with the MINI TREK RX 1.20 mm balloon,
- Achieve a final TIMI flow grade of 3 at the conclusion of the PCI procedure for the lesion.

The secondary endpoints of device success and lesion success were analyzed on a per lesion basis. Other secondary endpoints included individual procedural parameters, in-hospital major adverse cardiac events (MACE) and in-hospital target lesion failure (TLF) and in-hospital stent thrombosis (ST).

Device success was defined as meeting all the following after single or multiple attempts:

- Successful delivery of the MINI TREK RX 1.20 mm balloon to and across the target lesion,
- Successful dilatation with the MINI TREK RX 1.20 mm balloon as defined by improvement in minimal lumen diameter (MLD) based on core lab analysis, and

- No vessel perforation, no flow-limiting dissection, no reduction in TIMI flow from baseline, and no clinically significant arrhythmias that required medical treatment or device intervention following dilatation with the MINI TREK RX 1.20 mm balloon.

Lesion success was defined as meeting all the following after single or multiple attempts:

- Successful dilatation with any device(s) defined as achieving a final residual percent diameter stenosis of < 50%,
- No vessel perforation, no flow-limiting vessel dissection, no reduction in TIMI flow from baseline, and no clinically significant arrhythmias that required medical treatment or device intervention following dilatation with any device,
- Achievement of a final TIMI flow grade of 3 at the conclusion of the PCI procedure for the lesion.

Clinical follow-up was between post-procedure to hospital discharge.

14.3.4 Demographics and Lesion Characteristics

The mean age of the study population was 64.75 ± 10.95 years, of which 70.4% (50/71) were male and 29.6% (21/71) were female. Among the 83 target lesions assessed, 75.9% (63/83) de novo and 24.1% (20/83) were restenotic. A total of 9.6% (8/83) of the lesions were located in saphenous vein bypass grafts per angiographic core lab assessment.

14.3.5 Clinical Results

A total of 71 subjects with 83 target lesions were enrolled. Angiographic documentation associated with the use of MINI TREK RX 1.20 mm required for endpoint analysis was available for 67 subjects with 78 target lesions. The analysis of the primary endpoint was summarized at the subject level. The analyses of the secondary endpoints of Device Success and Lesion Success were both summarized at the lesion level. The primary and key secondary results are presented in **Table 2-3** and **Table 2-4**. All the analyses were performed on the intent-to-treat (ITT) population and were descriptive. An additional analysis on a subgroup of 52 subjects who had at least a CK-MB draw at or later than 16 hours post-index procedure was also performed for clinical endpoints, including In-hospital MACE, TLF, and ST.

The primary endpoint, procedure success, was achieved in 98.5% (66/67) of the subjects. For the individual criteria within procedure success, 100.0% (71/71) of subjects had successful delivery of the MINI TREK RX 1.20 mm balloon, 100 % (71/71) had successful inflation and deflation of the balloon, 0.0% (0/67) had protocol-specified procedural complications following the dilatation with the balloon, and 98.6% (70/71) had final TIMI 3 flow at the conclusion of the PCI procedure.

Table 2-3 Efficacy Measures

Primary Endpoint	**MINI TREK (N=71)**
Procedure Success	98.5% (66/67)
Secondary Endpoints	**MINI TREK (M=83)**
Device Success	96.2% (75/78)
Lesion Success	97.6% (81/33)

Note: N = Number of Subjects, M = Number of Lesions
Note: Angiographic documentation associated with the use of MINI TREK RX 1.20 mm was available for 67 subjects with 78 target lesions.

For clinical endpoints, in the analysis of the ITT population, the in-hospital MACE and TLF rates were both 8.5% (6/71), driven solely by periprocedural MI (8.5%) per Academic Research Consortium (ARC) definition. In the additional analysis of the subgroup of the 52 subjects, the in-hospital MACE and TLF rates were both 9.6% (5/52), driven solely by periprocedural MI (9.6%) per ACR definition. All MIs were non-Q wave. There was no in-hospital stent thrombosis per ARC (definite/probable) in both the analyses of the ITT population and the subgroup of the 52 subjects. There were also no vessel perforations, flow-limiting vessel dissections, thrombus in the target vessel, balloon rupture or clinically significant arrhythmias post-MINI TREK usage or post-procedure.

Table 2-4 In-Hospital Adverse Events

	MINI TREK (N=71)	**MINI TREK (N=52)[1]**
In-Hospital Composite Endpoints		
MACE (all death, all MI, CI-TLR)	8.5% (6/71)	9.6% (5/52)
TLF (cardiac death, target vessel MI, CI-TLR)	8.5% (6/71)	9.6% (5/52)
In-Hospital Component Endpoints		
All Death	0% (0/71)	0% (0/52)
Cardiac Death	0% (0/71)	0% (0/52)
All MI	8.5% (6/71)	9.6% (5/52)
TV MI	8.5% (6/71)	9.6% (5/52)
CI TLR (CABG/PCI)	0% (0/71)	0% (0/52)
Stent Thrombosis Acute/Subacute (0-30 days)[2]		
Definite/Probable	0% (0/64)	0% (0/49)

[1]These include 52 subjects with at least one CK-MB draw at or later than 16 hours post-procedure.
[2]Data were captured up to in-hospital only.
Note: Subjects are only counted once for each type of event.
Note: This table includes TLR on both lesions for subjects with two target lesions treated.
Note: In-hospital is definec as post index procedure hospitalization prior to discharge.
Note: CI indicates clinically indicated.

14.3.6 Conclusion

The primary endpoint, procedure success, was achieved in 98.5% of the 67 subjects with available data for analysis. The secondary success endpoints, device success and lesion success, were achieved in 96.2% and 97.6% of the target lesions with available data for

analysis. These overall high success rates demonstrate the MINI TREK RX 1.20 mm is effective in pre-dilating stenotic lesions.

In this trial, acceptably low rates of adverse events were reported. There were no protocol-specified acute procedure complications associated with the use of MINI TREK RX 1.20 mm or any device. There was also no reported in-hospital stent thrombosis. In-hospital MACE and in-hospital TLF rates were both 8.5% (6/71) in the analysis of the ITT population and were both 9.6% in the subgroup analysis of the 52 subjects, driven solely by periprocedural non-Q-wave MI per ARC definition. As a final perspective, MI is a component of MACE and TLF which are secondary endpoints in this trail. Taken together, the lack of protocol-specified acute procedure complications and in-hospital stent thrombosis and the low in-hospital MACE and TLF rates support the acute safety of MINI TREK RX 1.20 mm in pre-dilating stenotic lesions.

In conclusion, the acute safety and efficacy data presented in this report demonstrate the MINI TREK RX 1.20 mm may be used as a pre-dilatation catheter to successfully enlarge coronary luminal diameters during PCI procedures.

14.4 Performance Testing - Conclusion

These biocompatibility, *in vitro* bench testing and clinical study results demonstrated that the MINI TREK RX 1.20 mm and MINI TREK OTW 1.20 mm Coronary Dilatation Catheters met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and, therefore, these devices may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular
c/o Ms. Suzanne Redman
Principal Regulatory Affairs Associate
26531 Ynez Road
Temecula, CA 92591

JUN - 2 2011

Re: K110617
Trade/Device Name: MINI TREK™ RX 1.20 mm Coronary Dilation Catheter
MINI TREK™ OTW 1.20 mm Coronary Dilation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: PTCA Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: May 16, 2011
Received: May 17, 2011

Dear Ms. Redman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1 – INDICATIONS FOR USE

510(k) Number (if known): K110617

Device Names: MINI TREK™ RX 1.20 mm Coronary Dilatation Catheter
MINI TREK™ OTW 1.20 mm Coronary Dilatation Catheter

Indications for Use: The MINI TREK™ RX 1.20 mm Coronary Dilatation Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).

The MINI TREK™ OTW 1.20 mm Coronary Dilatation Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).

Prescription Use____X____ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110617

Page 1 of 1